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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10:001,876

11/20/2001

Susana Salceda

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EXAMINER

SPIEGLER, ALEXANDER H

ART UNIT

PAPER NUMBER

1637

67

DATE MAILED: 06/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/001,876

Applicant(s)

SALCEDA ET AL.

Examiner

Alexander H. Spiegler

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 08 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-5, 7-9 and 15 is/are pending in the application.
- 4a) Of the above claim(s) 6, 10-14, 16 and 17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-5, 7-9 and 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I (claims 1-5, 7-9 and 15, and SEQ ID NO: 27) in Paper No. 8, filed May 8, 2003 is acknowledged.

The traversal is on the ground(s) that the groups are directed to subject matter that is closely interrelated and therefore examination of all of the groups would not place an undue burden on the Examiner. This is not found persuasive because it is maintained that undue burden would be required to examine the claims of Groups II-IX along with the claims of Group I. For purposes of the initial requirement, a serious or undue burden on the examiner may be shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search as defined in MPEP§ 808.02. The serious burden of search has been established, at least, by the different classifications of the inventions (see previous Office Action). Accordingly, the restriction requirement is made FINAL.

Claims 1-5, 7-9 and 15 have been examined on the merits; claims 6, 10-14 and 16-17 have been withdrawn as being drawn to a non-elected invention.

Information Disclosure Statement

2. The information disclosure statement of Paper No. 6 complies with CFR 1.97, 1.98, and M.P.E.P. 609, and has been considered.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. Claims 1-5, 7-9 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-5, 7-9 and 15 over "selectively hybridizes" because it is not clear as to what is meant by "selectively hybridizes". That is, it is not clear as to what conditions are required for "selective hybridization", and the specification does not specifically define what conditions are necessary for "selective hybridization". Applicants should amend the claims to specify the specific conditions (e.g., xSSC, temperature, etc.).

Claim Rejections - 35 USC § 101

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 1-5, 7-9 and 15 rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a substantial asserted utility or a well established utility.

The pending claims have been reviewed in light of the Utility Examination Guidelines in the Federal Register, Vol. 66, No. 4, pages 1092-1099, Friday, January 5, 2001, as well as the MPEP and existing law.

I. *The specification does not assert a substantial utility because the utilities asserted by Applicants requires or constitutes carrying out further research to identify or reasonably confirm a "real world" use.*

MPEP § 2107.01 states:

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A "substantial utility" defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities.

Applicants alleged the following utilities:

- The present invention relates newly identified nucleic acid molecules and polypeptides present in normal and neoplastic prostate cells...The present invention also relates to compositions comprising the nucleic acids...of the inventions and methods of use of these compositions. These uses include identifying, diagnosing, monitoring, staging, imaging, and treating prostate cancer and non-cancerous disease states in prostate tissue, identifying prostate tissue...The uses also include gene therapy, production of transgenic animals and cells, and production of engineered prostate tissue for treatment and research (pg. 1, ln. 9-21, but see also pgs. 99-105 and 111-113).
- The isolated nucleic acid molecules of the present invention can be used as hybridization probes to detect, characterize, and quantify hybridizing nucleic acids in and isolate hybridizing nucleic acids from, both genomic and transcript-derived nucleic acid samples (pg. 40, ln. 26-30).
- [A] nucleic acid molecule of the invention may be used as a probe or primer to identify or amplify a second nucleic acid molecule that selectively hybridizes to the nucleic acid molecule of the invention (pg. 42, ln. 4-6).

In summary, Applicants allege the claimed nucleic acid of the present invention (i.e., SEQ ID NO: 27) can be used in methods of detecting, diagnosing and treating prostate cancer, as well as, for use in hybridization and amplification assays, wherein SEQ ID NO: 27 can be used as a primer or probe for an unspecified gene, gene fragment or gene product.

The specification teaches an mRNA subtraction analysis was carried out, and following said analysis, gene expression was quantified (Ex. 1-2, pgs. 116-123).

The specification states:

[T]he level of mRNA expression in cancer samples and the isogenic normal adjacent tissue from the same individual are compared. This comparison provides an indication of specificity for the cancer stage (e.g., higher levels of mRNA expression in the cancer

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plus the mRNA overexpression in matching samples are indicative of SEQ ID NO: 1 through 112 being diagnostic markers for cancer.

The specification teaches an example of expression analysis, wherein Sqpro045 (SEQ ID NO: 77) appears to be overexpressed in prostate tissue in prostate cancer samples, as compared to normal samples; and additionally, SEQ ID NO: 77 appears to be overexpressed in prostate tissue compared to other tissues of prostate cancer samples (pgs. 121-123).

However, the specification is silent as to any teachings, results or correlations between the claimed nucleic acid (SEQ ID NO: 27) and prostate cancer.

In order for a nucleic acid to be useful for detection, diagnosis and/or treatment of a disease, there must be a well-established or disclosed correlation or relationship between the claimed nucleic acid and a disease or disorder. The presence of a nucleic acid in tissue that is derived from cancer cells is not sufficient for establishing a utility in diagnosis of disease in the absence of some information regarding a correlative or causal relationship between the expression of the claimed cDNA and the disease. If a molecule is to be used as a surrogate for a disease state, some disease state must be identified in some way with the molecule. There must be some expression pattern that would allow the claimed nucleic acid to be used in a diagnostic manner. Many nucleic acids are expressed in normal tissues and diseased tissues. Therefore, one needs to know, e.g., that the claimed nucleic acid is either present only in cancer tissue to the exclusion of normal tissue or is expressed in higher levels in diseased tissue compared to normal tissue (i.e. overexpression). Evidence of a differential expression might serve as a basis for use of the claimed nucleic acid as a diagnostic for a disease. However, in the absence of any disclosed relationship between the claimed polynucleotide or the protein that is encoded thereby and any disease or disorder and the lack of any correlation between the claimed polynucleotide or the encoded protein with any known disease or disorder, any information obtained from an

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"Congress intended that no patent be granted on a chemical compound whose sole 'utility' consists of its potential role as an object of use-testing." *Brenner*, 148 USPQ at 696.

In the instant case, the specification does not teach any relationship between the claimed nucleic acid and prostate cancer. At best, Applicants have proposed a starting point for further research in order to determine whether SEQ ID NO: 27 is correlated with prostate cancer. Accordingly, the disclosure does not present a substantial utility that would support the requirement of 35 U.S.C. §101.

II. *The specification is not supported by a well-established utility because one of ordinary skill in the art would not immediately appreciate why the invention is useful based on the characteristics on the invention.*

MPEP 2107 states:

"An invention has a well-established utility if (i) a person of ordinary skill in the art would immediately appreciate why the invention is useful based on the characteristics of the invention (e.g., properties or applications of a product or process), and (ii) the utility is specific, substantial, and credible."

Applicants have provided little to no evidence of the characteristics of the specifically claimed nucleic acid, the specification is not substantial, and based on Applicants assertion that the claimed nucleic acid is new, it is not apparent as to how "a person of ordinary skill in the art would immediately appreciate why the invention is useful". This is evidenced by the fact that further research would need to be carried out by the skilled artisan even given Applicants' claimed nucleic acid. For these reasons, the specification is not supported by a well-established utility.

Finally, MPEP § 2107 states:

"The 35 U.S.C. 101 and 112 rejections shift the burden of coming forward with evidence to the applicant to:

(i) Explicitly identify a specific and substantial utility for the claimed invention; and

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(ii) Provide evidence that one of ordinary skill in the art would have recognized that the identified specific and substantial utility was well-established **at the time of filing**".

In the instant case, Applicants have not "explicitly identifi[ed] a substantial utility for the claimed invention". Furthermore, the specification has not provided any evidence that "one of ordinary skill in the art would have recognized that the identified specific and substantial utility was well-established **at the time of filing**".

Accordingly, the claimed invention lacks a substantial utility, or in the alternative, a well-established utility.

Claim Rejections - 35 USC § 112

7. Claims 1-5, 7-9 and 15 also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1-5, 7-9 and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

35 U.S.C. § 112, requires, *inter alia*, that a patent specification contain a written description of the invention and the manner and process of making and using it "in such full

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clear and concise terms as to enable one skilled in the art... to make and use" the invention.

While it is well settled that a patent application need not teach each possible embodiment of the claimed invention, it is manifestly true that written description cannot be settled by reliance on that which has not been achieved in the art, or that which is not disclosed in the specification.

That is, a specification is not considered to satisfy the requirement for an adequate written description if it fails to disclose the specific starting materials or conditions for making the invention. (*Genentech, Inc. v. Novo Nordisk*, 108 F3d. 1361, 42 USPQ2d 100. Fed. Cir. 1997), or evidence that the applicants at the time the application was filed, has possession of the claimed invention.

Applicant's attention is also drawn to the "Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, 1st Paragraph, Written Description Requirement" (published in Federal Register/Vol. 66, No. 4/Friday, January 5, 2001/Notices; p. 1099-1111).

Claims 1-5, 7-9 and 15 are directed to nucleic acids comprising SEQ ID NO: 27, nucleic acids having at least 60% sequence identity to SEQ ID NO: 27, and nucleic acid molecules that "selectively hybridize" to SEQ ID NO: 27.

Applicants disclose SEQ ID NO: 27. However, it is not clear as to whether this is a full-length gene or partial cDNA sequence.

Claims reciting "comprising", "at least 60% sequence identity" or nucleic acids that "selectively hybridize" to SEQ ID NO: 27 are inclusive of sequences from other species, mutated sequences, allelic variants and full-length genes, for example, which have different functions than that of the nucleic acid in SEQ ID NO: 27.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in *possession* of the invention. The invention is, for purposes of the written description inquiry, *whatever is now claimed* (See page 1117)." The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed (See Vas-Cath at page 1116)."

Possession may be shown in many ways. For example, possession may be shown, *inter alia*, by describing an actual reduction to practice of the claimed invention. Possession may also be shown by a clear depiction of the invention in detailed drawings or in structural chemical formulas, which permit a person skilled in the art to clearly recognize, that applicant had possession of the claimed invention. An adequate written description of the invention may be shown by any description of sufficient, relevant, identifying characteristics so long as a person skilled in the art would recognize that the inventor had possession of the claimed invention...

Factors to be considered in determining whether there is sufficient evidence of possession include the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient. (Written Description Guidelines, pgs. 1105-1106).

In the instant case, Applicants have not described any sufficient, relevant, identifying characteristics, wherein a person skilled in the art would recognize that the inventor had possession of the claimed invention. Applicants have described only SEQ ID NO: 27. This disclosure of a single species does not provide an adequate written description and is not representative of the broadly claimed genus. Accordingly, the specification provides an insufficient written description to support the genus encompassed by the claims.

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It is noted, Applicants should specify whether SEQ ID NO: 27 is a full-length cDNA, and when claims are drawn to % identity, Applicants should amend the claims to recite functional language.

Conclusion

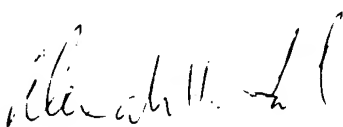
10. No claims are allowable.

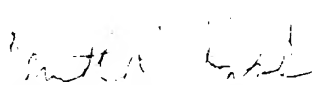
Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander H. Spiegler whose telephone number is (703) 305-0806. The examiner can normally be reached on Monday through Friday, 7:00 AM to 3:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014. Applicant is also invited to contact the TC 1600 Customer Service Hotline at (703) 308-0198.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


Alexander H. Spiegler
June 16, 2003


KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER
